

WOUND PACKING FOR PREVENTING WOUND CLOSURE

BACKGROUND OF THE INVENTION

5 The present disclosure relates to bandages for wounds, and in some instances, to bandages for use with a vacuum and/or irrigation source. Specifically, the present disclosure relates to wound packing used with vacuum bandages or other types of bandages to keep a wound from closing in an unwanted manner.

10 The prior art contemplates that chronic wounds may be treated by providing a vacuum in the space above the wound to promote healing. A number of prior art references teach the value of the vacuum bandage or the provision of vacuum in the space above the surface of a chronic wound.

15 A vacuum bandage is a bandage having a cover for sealing about the outer perimeter of the wound and under which a vacuum is established to act on the wound surface. Applying vacuum to the wound surface promotes healing of chronic wounds. Typically, suction tubes are provided for drawing exudate away from the wound and for creating a vacuum under the cover. The following U.S. Patents establish the nature of vacuum treatment bandages and devices: 6,095,992, 6,080,189, 6,071,304, 5,645,081, 5,636,643, 5,358,494, 5,298,015, 4,969,880, 4,655,754, 4,569,674, 4,382,441, and 4,112,947. All of such references are incorporated herein  
20 by reference.

Further, the prior art contemplates that wounds may be treated by providing irrigation in the space above the wound. Typically, a tube is provided in communication with the wound surface of the wound at one end and with an irrigation source at another end. The fluid from the irrigation source travels through  
25 the tube to the wound surface.

Additionally, it is desirable to keep wound surfaces separated in some types of wounds. For example, after sinus surgery, certain wound surfaces should be separated to prevent closure of the wound in an unwanted manner.

30 SUMMARY OF THE INVENTION

The present invention comprises one or more of the following features, discussed below, or any combination thereof.

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According to the present disclosure, several embodiments of wound packing for preventing wound closure in an unwanted manner are provided. In some embodiments, a vacuum bandage system is provided for use with a wound having a wound surface. The vacuum bandage system may include a wound dressing member and a wound insert. The wound dressing member may include a plurality of holes and a port in communication with the holes. The port may also be configured to be coupled to a vacuum source. The wound insert may be configured for placement within the wound between the wound surface and the wound dressing member. The wound insert may be made of a material which is not porous or foam-like.

10           The wound insert may be thin and flexible and may include a plurality of discrete passageways. The passageways may be in communication with the vacuum source. The passageways of the wound insert may be conduits through the wound insert or the passageways may comprise channels formed in each of a top and bottom surface of the insert.

15           In an illustrative embodiment, the insert is cylindrical in shape and is made of approximately 50 durometer silicone. Such an insert may have a diameter of approximately 0.0925 inch (2.35 mm).

          Further according to the present disclosure, a method of treating a wound having a wound tunnel is provided. The method may include placing a non-porous wound insert within a tunneled portion of a wound and placing a wound dressing member over the wound insert so that the wound insert is positioned between a wound surface of the wound and the wound dressing member. The method further may include coupling the wound dressing member to a vacuum source, placing a sealing film over the wound dressing member for attachment to healthy skin surrounding the wound, and creating a negative pressure between the sealing film and a surface of the wound.

          The wound inserts or packing disclosed herein may be used with all types of wounds and bandages. Thus, such wound packing may be used with regular bandages and/or vacuum bandages and/or irrigation bandages.

30           Features of the present invention will become apparent to those skilled in the art upon consideration of the following detailed description of the preferred embodiments exemplifying the best mode of carrying out the invention as presently

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perceived.

## BRIEF DESCRIPTION OF THE DRAWINGS

The detailed description particularly refers to the accompanying  
5 figures in which:

Fig. 1 is a part perspective, part diagrammatic view of a wound care bandage system showing a vacuum bandage located on the leg of a patient, and a vacuum source and an irrigation source coupled to the bandage through the use of a switch valve;

10 Fig. 2 is a sectional view of the vacuum bandage of the system of Fig. 1 coupled to a tunneled wound of a patient showing a wound dressing member of the system covering the tunneled wound, a tube coupling the member to the vacuum and irrigation sources (not shown), and an illustrative wound insert of the system rolled and positioned within the tunneled wound below the member to help prevent portions  
15 of the tunneled wound from prematurely healing together;

Fig. 3 is a sectional view of another illustrative vacuum bandage of the system of Fig. 1 coupled to an undermined wound of a patient showing the wound dressing member covering the undermined wound and additional illustrative wound inserts for use with the system positioned within the undermined wound;

20 Fig. 4 is a perspective view of another illustrative wound insert showing intersecting passageways or conduits of the insert;

Fig. 5 is a perspective view of yet another illustrative wound insert, similar to the insert shown in Fig. 4, showing through holes located at the intersections of the internal conduits for communication with the internal conduits;

25 Fig. 6 is a perspective view of yet another illustrative wound insert showing internal conduits along only a length of the insert;

Fig. 7 is a perspective view of still another illustrative wound insert showing internal conduits along a length of the insert and through holes generally perpendicular to the conduits and in communication with the conduits;

30 Fig. 8 is a perspective view of the wound insert of Fig. 2 showing external channels formed in both a top and bottom surface of the insert;

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Fig. 9 is a perspective view of the wound insert of Fig. 3 showing external channels formed in top and bottom surfaces of the insert and further showing through holes in communication with the channels;

Fig. 10 is a top plan view of the wound insert shown in Figs 2 and 8 showing the insert rolled along its length for insertion within a wound tunnel of a wound, for example;

Fig. 11 is a perspective view of still another illustrative wound insert showing intersecting external channels of the insert along both a length and width of the insert;

Fig. 12 is a perspective view of yet another illustrative wound insert showing intersecting external channels and through holes in communication with the channels;

Fig. 13 is a perspective view of another illustrative wound insert being tube-shaped and including holes through a body of the insert in communication with a central passageway of the insert;

Fig. 14 is a perspective view of another illustrative wound insert showing a long, cylindrical, solid rod-shape of the insert; and

Fig. 15 is a top plan view of a group of the rod-shaped inserts of Fig. 14 as they are illustratively manufactured by extension molding, for example.

#### DETAILED DESCRIPTION OF THE DRAWINGS

A wound care bandage system 10 is provided for use with a wound 12, and specifically for use with a wound tunnel 14 of wound 12 (as shown in Fig. 2) and with undermined portions 16 of wound 12 (as shown in Fig. 3). As illustratively shown in Fig. 1, system 10 includes a vacuum bandage 18, a vacuum source 20 coupled to bandage 18, an irrigation source 22 coupled to bandage 18, and a valve 24 to provide selective communication between wound 12 and vacuum and irrigation sources 20, 22. System 10 further includes a wound insert or packing, illustrative embodiments of which are shown in Figs. 4-15. Although the illustrative wound packing of Figs. 4-15 are described herein as being used with system 10 having a vacuum source 20 and an irrigation source 22, it is within the scope of this disclosure for the wound inserts disclosed herein to be used alone or in regular bandages that do

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not have sources 20, 22 associated therewith or in bandages having only one or the other of sources 20, 22 associated therewith.

In some uses, wound inserts are provided to generally fill the open space created by various wound tunnels 14 and/or undermined portions 16 of wounds 12. Such wound tunnels 14 and undermined portions 16 are generally ulcerated portions of wound 12. Wound inserts help to maintain the opening created by the wound tunnels 14 and/or undermined portions 16 until the wound 12 can properly heal on its own. Further, wound inserts force the wound openings to heal generally evenly so that side and bottom surfaces 15 of wound tunnels 14 and side to bottom surfaces 17 of undermined portions 16 gradually heal toward each other to progressively shrink the open space. This may also help to prevent a "bridge" of granulations from forming across the open space and effectively sealing off an ulcerated portion of the of wound 12, thus preventing the sealed-off area from being able to be treated by the vacuum and/or irrigation of system 10.

Vacuum bandage 18, as shown in Fig. 1, is provided for use with the wound 12 and is sealed about the wound 12 by a cover or sealing film 13 of bandage 18 to create a sealed environment between the wound 12 and sealing film 13 in which a negative pressure can be established. As mentioned above, bandage 18 is selectively coupled to both vacuum source 20 and irrigation source 22 through the use of valve 24. It is within the scope of this disclosure, however, to have only a vacuum source coupled to bandage 18 or to omit both sources 20, 22.

System 10 promotes the healing of the wound 12 by providing vacuum therapy to the wound to promote blood flow and remove exudate from the wound surfaces 15, 17 of illustrative wound tunnel 14 and undermined portions 16 and by providing for irrigation of the wound 12 with fluids such as saline, for example. An illustrative wound treatment apparatus having a wound temperature control system, a medicine delivery system, and a drainage system is disclosed in U.S. Patent No. 6,458,109. An illustrative vacuum and irrigation system is disclosed in U.S. Patent Publication No. US 2002/0161317 A1. Additionally, an illustrative vacuum bandage is disclosed in U.S. Patent Publication No. US 2002/0065494 A1.

Alternative vacuum bandages are disclosed in U.S. Patent Publication No. US 2002/0082567 A1. Further, a vacuum bandage system including a controller of the system is disclosed in U.S. Application No. 10/159,583, filed on May 31, 2002,

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titled WOUND TREATMENT APPARATUS and in U.S. Application No. 60/394,970 filed on May 31, 2002, titled WOUND TREATMENT APPARATUS. All of the applications mentioned in this and the preceding paragraph are hereby incorporated herein by reference.

5                   As shown in Fig. 4, an illustrative wound insert 26 is provided for use with system 10 and bandage 18. Wound insert 26 includes a generally thin and flexible body 28 having a top surface 30, a bottom surface 32, and side surfaces 34. Insert 26 is made of a medical grade silicone or other type of elastomer which is pliable. Two companies, for example, which manufacture such medical grade  
10                   silicone are GE Silicones and NuSil Technology. It is within the scope of this disclosure, however, to include a wound insert made of any type of thin, flexible material that is non-porous, meaning that the material is generally non-foam-like. This thin, flexible material is also generally non-absorptive. For example, materials such as polyvinylchloride (PVC), PVC free of diethylhexyl phthalate (DEHP-free  
15                   PVC), polyurethane, or polyethylene may be used in the manufacture of insert 26.

                  Further, insert 26 may be molded to include anti-microbial constituents. For example, it is within the scope of this disclosure to impregnate insert 26 with silver ions which are known anti-microbials. The following PCT publications illustrate the use of anti-microbials in various products and are  
20                   incorporated herein by reference: "Antimicrobial Plastic Closures for Drinking Containers", WO 00/26100; "Antimicrobial Contact Lens Case", WO 00/038552; "Antimicrobial Fabric and Medical Graft of the Fabric", WO 00/32247; "Antimicrobial Suturing Ring for Heart Valve", WO 00/30567.

                  Insert 26 is also made of a generally non-adhesive material. Therefore,  
25                   portions of insert 26 which may abut wound surfaces 15, 17 of wound tunnel 14 and/or undermined portions 16 of wound 12 do not adhere to the wound surfaces 15, 17. Further, insert 26 is solid in nature and generally non-compressible. For example, when a negative pressure is applied to insert 26, a thickness of insert 26 remains relatively constant.

30                   As shown in Fig. 4, top, bottom, and side surfaces 30, 32, 34 are generally smooth. It is within the scope of this disclosure, however, for one or more surfaces of insert 26 to be texturized or to include one or more ribs, protrusions, spacers, etc. Body 28 of insert 26 further includes passageways or conduits 38

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running through body 28 along a length 40 and a width 42 of insert 26. Conduits 38 form openings 44 defined in each side surface 34 of body 28. As shown in Fig. 4, conduits 38 running along length 40 and width 42 of insert 26 lie in the same plane and therefore intersect each other at junctions 46. It is within the scope of this disclosure, however, for insert 26 to include one or more conduits 38 positioned to lie in separate planes, such as parallel planes, for example so as not to intersect. Further, it is within the scope of this disclosure for insert 26 to include any number of conduits 38 running along the length 40 and/or width 42 of insert 26. Further, conduits 38 may run along the length 40 only (as shown in Fig. 6), width 42 only, or conduits 38 may run diagonally or at any angle through body 28. Further, conduits 38 may be curved or wavy, for example, rather than generally straight as illustrated in Fig. 4.

Length 40 of illustrative insert 26 may be up to about 30 mm and width 42 of insert 26 may also be up to about 30 mm. Further, a thickness 43 of insert 26 may be within the range of about 1 mm to about 15 mm, for example. Although illustrative insert 26 has the above-mentioned dimensions, it is within the scope of this disclosure for insert 26 (an similar alternative inserts described below) to have other suitable dimensions for treating wounds and particularly for treating tunneled and/or undermined portions of wounds in a vacuum therapy system. Further, although insert 26 may be formed having certain dimensions, it is within the scope of this disclosure for a caregiver to trim insert 26 to fit a particular wound.

Another illustrative insert 126 is shown in Fig. 5. Insert 126 is similar to insert 26. Therefore, like reference numerals have been used for similar components or features. The only difference between insert 26 and insert 126 is that insert 126 includes generally vertical conduits or through holes 138 positioned at junctions 46 for communication with intersecting conduits 38 along the length 40 and width 42 of body 28. Conduits 138 form openings 144 defined in each of the top and bottom surfaces 30, 32 of body 28. It is also within the scope of this disclosure for conduits 138 of insert 126 to be located at areas other than junctions 46 of conduits 38.

As mentioned above, another illustrative insert 226 is provided in Fig. 6 where insert 226 includes conduits 38 only along length 40 of body 28. Fig. 7 shows yet another illustrative insert 326, similar to insert 226, and further including through holes 138 positioned at spaced apart intervals along each conduit 38.

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Conduits 38 run along length 40 of body 28 and each through hole 138 forms opening 144 in top and bottom surfaces 30, 32 of body 28. In alternative embodiments, through holes 138 are spaced from conduits 38.

As shown in Fig. 8, another alternative insert 426 is provided including top, bottom, and side surfaces 30, 32, 34. Insert 426 is similar to the inserts described above, however, illustrative insert 426 does not include conduits 38 or 138. Insert 426 does include passageways or channels 438 formed in top and bottom surfaces 30, 32. Illustratively, channels 438 run along length 40 of insert 426. Further illustratively, channels 438 of top and bottom surface 30, 32 are alternately spaced along width 42 of insert 426 so that a bottom channel 438 is generally not positioned directly below a top channel 438. Illustratively, channels 438 have a generally semi-circular or curved profile and define a curved surface 440. Although illustrative channels 438 are generally straight along length 40, it is within the scope of this disclosure to include channels that are wavy, zig-zagged, etc., or channels that run at an angle to the length 40 and/or width 42 of insert 426.

Still another alternative insert 526 is shown in Fig. 9. Insert 526 is similar to insert 426, shown in Fig. 8, however, insert 526 further includes vertical conduits or through holes 138 forming openings 144 in top and bottom surfaces 30, 32 of body 28 to communicate with channels 438 formed in each of the top and bottom surfaces 30, 32.

Looking now to Fig. 11, a wound insert 626 is provided. Wound insert 626 includes both "lengthwise and widthwise" channels 438 running along the length 40 and width 42 of body 28. Each of the "lengthwise and widthwise" channels 438 is formed in top and bottom surfaces 30, 32 of body 28 and is alternately spaced thereon. The channels 438 intersect each other at junctions 646.

Another illustrative wound insert 726 is shown in Fig. 12. Wound insert 726 includes all the features of wound insert 626 (shown in Fig. 11), such as vertical and horizontal channels 438 formed in top and bottom surfaces 30, 32 of body 28. Wound insert 726 further includes vertical conduits 138 at junctions 646 of each of the vertical and horizontal channels 438 formed in top surface 30 of body 28. It is within the scope of this disclosure to further include through holes 138 at junctions (not shown) of each of the vertical and horizontal channels 438 formed in bottom surface 32. It is further within the scope of this disclosure to include through holes

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138 in communication with one or more channels 438 at areas other than junctions 646.

As is described above, various illustrative wound inserts 26, 126, 226, 326, 426, 526, 626, 726 are provided for use with a vacuum bandage or with other types of bandages or alone (i.e., without other bandage components). Illustrative inserts are all thin and flexible and generally rectangularly shaped, although, it is within the scope of this disclosure to include thin, flexible inserts of any suitable shape such as circular, triangular, oval, etc. In addition, a caregiver may trim any of the disclosed inserts to a desired shape using scissors, for example. Further, all inserts described above include passageways such as conduits 38, through holes 138, and/or channels 438. In some embodiments, the passageways are provided to communicate negative pressure from vacuum source 20, or fluid from irrigation source 22, to tunneled portions 14 or undermined portions 16 of wound 12.

Yet another illustrative insert 826 is shown in Fig. 13. Insert 826 is made of the same thin, flexible material as the inserts described above. However, body 828 of insert 826 is formed in the shape of a hollow cylinder forming a central conduit 838 therethrough. Insert 826 includes passageways or through holes 844 formed through body 828 to communicate with central conduit 838. Illustratively, holes 844 are arranged in rows along a length 840 of insert 826. It is within the scope of this disclosure, however, for holes 844 to be arranged in any random or non-random pattern.

Still another insert 926 is shown in Fig. 14. Illustratively, insert 926 is rod-shaped and has a generally circular profile. Each insert 926 is solid, although, it is within the scope of this disclosure to drill or otherwise form holes or passageways through insert 926. Illustratively, each insert 926 has a diameter 927 of 0.0925 inch (2.350 mm). It is within the scope of this disclosure for insert 926 to have any suitable diameter for use with tunneled wounds 14. Inserts 926 are manufactured by extruding the material into circular rods attached to each other by a small web of material 928, as shown in Fig. 15, for example. Illustratively, web 928 is 0.005 inch (0.127 mm) from rod to rod. Further, as illustratively shown in Fig. 15, twenty-three inserts 926 are extruded simultaneously. Each insert 926 is positioned at a 15° angle to adjoining inserts. Web 928 connects inserts 926 to each other to allow multiple inserts to be extruded simultaneously. Further, web 928 is sufficiently small to allow

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a user to separate, by pulling, for example, each insert away from the nearest adjoining insert(s).

Inserts 926 may be extruded to any suitable length. Further, a caregiver dressing a particular tunneled wound 14 may further trim inserts 926 to an appropriate length. Inserts 926 are made from the same material described above with respect to the other inserts of the present disclosure. Each insert 926 includes a cylindrical body 929, a first end 930, and a second end 932 (shown in Fig. 14). In use, multiple inserts 926 may be inserted into a tunneled wound 14 to maintain the opening of the tunneled wound 14 until the wound is able to sufficiently heal properly. Although insert 926 is primarily described herein for use with tunneled portions 14 of wound 12, it is within the scope of this disclosure to use insert 926 with undermined portions 16 of wounds 12 as well. Further, it is within the scope of this disclosure for the profile of insert 926 to be a shape other than circular, such as square-shaped, triangular, rectangular, diamond-shaped, oval-shaped, etc.

As mentioned above, wound inserts 26, 126, 226, 326, 426, 526, 626, 727, 826, 926 are provided for placement within a wound tunnel 14 and/or an undermined portion 16 of a wound 12, such as that illustrated in Figs. 2 and 3. Specifically, Fig. 2 illustrates the use of insert 426 inserted within a wound 12 having a wound tunnel 14 extending below a surface 50 of the skin.

Generally, prior to insertion within a wound tunnel 14, for example, the thin, flat inserts 26, 126, 226, 326, 426, 526, 626, 726 are rolled along their length 40. Fig. 10 illustrates an end view of insert 426 (shown in Fig. 8) after insert 426 has been rolled along its length 40 for insertion into tunneled portion 14 of wound 12, for example. Illustratively insert 426 is inserted into wound tunnel 14 to help prevent a portion of tunnel 14 from prematurely closing or forming a bridge across the tunnel 14. Although illustrative insert 426 is inserted within tunnel 14, it is within the scope of this disclosure to place any other insert into tunneled portion 14. The inserts are provided to effectively maintain the opening created by tunnel 14 to allow tunnel 14 to heal in a more consistent and controlled manner evenly reducing the size of the tunnel 14 from the outer surfaces 15 of tunnel 14 inward until tunnel 14 has completely healed.

It is also contemplated that, in some embodiments, illustrative inserts are in communication with vacuum source 20 through vacuum bandage 18 and

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therefore may communicate the suction or negative pressure from vacuum source 20 along the passageways of each insert to the bottom and side walls 15 of tunnel 14. This negative pressure may help draw exudate away from wound 12. The vacuum or negative pressure which draws blood from the body to the wound surface 15 and  
5 draws exudate from the wound 12 up through the respective insert and through portions of vacuum bandage 18 promotes the healing of wound 12. As wound 12 heals, granulations form along wound surface 15. Granulations, therefore, are the replacement within the wound bed of tissue lost.

As shown in Figs. 2 and 10, the thin, flexible, and generally flat inserts  
10 (such as inserts 26, 126, 226, 326, 426, 526, 626, 726) are rolled along their length 40 so that such inserts may be inserted within tunnel 14 to generally fill the space created by tunnel 14. Fig. 10, for example, shows an end of insert 426 (shown in Fig. 8) after having been rolled along its length 40 to form a spiral-like shape so that channels 438 are positioned to lie generally vertically when insert 426 is placed  
15 within tunnel 14, as shown in Fig. 2. Each insert 26, 126, 226, 326, 427, 526, 626, 726 may be rolled so that either the top surface 30 or the bottom surface 32 is adjacent to surfaces 15 of tunnel 14 once inserted therein. Further, it is within the scope of this disclosure to roll each insert along its width 42, or even at an angle to the length 40 and width 42, as well, so that the insert is formed into a tube-like shape insertable  
20 within tunnel 14.

Illustratively, it is not necessary for a caregiver to roll insert 826 (shown in Fig. 13) or insert 926 (shown in Figs. 14 and 15) prior to placing either insert 826, 926 within tunnel 14 because each insert 826, 926 is already tube-like in shape. Further, it is within the scope of this disclosure for a caregiver to trim each  
25 insert to size and insert to fit the tunneled or undermined portions 14, 16 of any wound 12. As discussed above, any number of inserts 926 may be inserted within wound tunnel 14 either individually, or connected by webs 928. Further, suction and/or irrigation fluids may be communicated to a bottom portion of wound tunnel 14 by spaces created between the inserts 926 within tunnel 14.

30 In the treatment of undermined portions 16 of wounds 12, it may not be necessary to roll an insert into a tube-like shape as is described above with respect to tunneled portions 14 of wounds 12. As is illustratively shown in Fig. 3, undermined portions 16 of wound 12 are filled by the use of two inserts 526 (shown

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in Fig. 3) where one insert 526 is positioned to lie on top of the other insert 526.

Although inserts 526 are shown in Fig. 3, it is within the scope of this disclosure to use any type of generally thin, flexible insert with the use of undermined or tunneled wounds. Inserts 526 generally fill a space created by undermined portions 16 of wound 12. It is also contemplated that cylindrically-shaped inserts 826 and 926 may be used to fill or pack undermined portions 16 as well.

As mentioned above, wound inserts of the present disclosure may be provided as part of vacuum bandage system 10 for use with a vacuum bandage 18 coupled to vacuum source 20. Bandage 18 may also be coupled to irrigation source 22, as shown in Fig. 1, for example. The illustrative vacuum bandage 18, shown in Figs. 1-3 includes a wound dressing member 52 adjacent wound 12 and sealing film 13 covering member 52 and sealed about member 52 and wound 12 to the patient's healthy skin 50 surrounding wound 12.

Illustrative member 52 of bandage 18 includes a smooth wound facing surface 54. Wound facing surface 54 may also be textured or roughened and/or may include spacers, ribs, protrusions, etc., extending from surface 54. Member 52 further includes opposite surface 56. Illustrative member 50 further includes a tube connector or port 58 coupled to opposite surface 56. Connector 58 is coupled to a tube 60 of system 10 in communication with vacuum and irrigation sources 20, 22. Member 50 also includes one or more passageways 62 formed between opposite surface 56 and wound facing surface 54. Each passageway 62 is in communication with connector 58 to communicate either negative pressure from vacuum source 20 to wound 12 or to communicate fluid from irrigation source 22 to wound 12. A plurality of holes 64 are illustratively provided through wound facing surface 54. Holes 64 communicate with wound 12 and passageways 62 as well. Further illustratively, wound member 52 is made of the same material as the various wound inserts described above. Although illustrative member 52 is provided, it is within the scope of this disclosure to include a vacuum bandage having any suitable type of wound dressing member having means for communicating negative pressure and/or irrigation fluid to the wound.

Although the invention has been described in detail with reference to certain embodiments, variations to modifications exist within the scope and spirit of the invention as described and defined in the following claims.